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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/757,288	01/14/2004	Yaron Keidar	BIO-173-CIP	4500

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EXAMINER

PEFFLEY, MICHAEL F

ART UNIT	PAPER NUMBER
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3739

DATE MAILED: 03/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	10/757,288		KEIDAR, YARON	
	Examiner		Art Unit	
	Michael Peffley		3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>12/9/04; 7/29/05</u> | 6) <input type="checkbox"/> Other: _____ |

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 16, 17, 21-23, 25-28, 30-40 and 42-48 are rejected under 35 U.S.C. 102(e) as being anticipated by Rittman, III et al (6,575,969).

Rittman, III et al disclose a system and method for ablating and imaging tissue. With regard to the apparatus (applicant's claims 25-48), the Rittman system includes a probe (Figure 1) which is adapted to be inserted into tissue. The probe itself may act as a sensor and used in conjunction with CT, MR, ultrasound and acoustic imaging to measure one or more local parameters and provide an image of the probe within the tissue. Additionally, the probe may be provide with thermal sensors for sensing local parameters in tissue (see Abstract and col. 12, lines 12-43). Rittman discloses an ablative device for providing a set dosage of energy, a display to show a map of the tissue being treated and a controller for generating images including predicted and actual ablation profiles (see Figure 6 and column 14). In particular, column 14, lines 9+ discusses that the image data may be fed into the computer system and used to represent the system in various ways, including displaying calculated outcomes based on tissue and energy levels for preplanning the settings as well as overlaid models to

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show the comparative pre-planned view with the actual ablated tissue image. The computer controls the delivery of energy based on input parameters such as temperature and image data (see col. 13). It is noted that applicant's apparatus claims are replete with recitation of elements "adapted" to perform various functions. The examiner maintains that the imaging and control system disclosed by Rittman is inherently capable of (i.e. "adapted to") performing the functions. Additionally and with respect to the method claims, Rittman specifically disclose the performance of these various steps, including providing a mapping imaging prior to ablation, providing an image of a predicted extent of the ablation profile, and providing an image of the actual ablation profile in comparison with the predicted profile image (col. 14).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 6-14, 16, 17, 19-23, 25-40 and 42-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al (2003/0109871) in view of the teaching of Rittman, III et al (6,575,969).

Johnson et al disclose a system and method for treating tissue comprising a probe (12) that is brought into contact with tissue, the probe having sensors for measuring one or more local parameters (e.g. impedance) of tissue in order to display a map of the tissue. Paragraph [0102] of the Johnson et al device addresses the use of

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mapping to show pre and post-surgical mapping of tissue during an ablation procedure using the sensors. Further, paragraph [0100] discloses the use of the sensors and mapping to control the delivery of ablation energy. Johnson et al fully disclose all the necessary display and control means for viewing, mapping and controlling the delivery of energy during the procedure. However, Johnson et al fail to specifically disclose a means to display a map of the predicted ablation of tissue for a given applied dosage, as well as means to display the actual ablation in comparison to the predicted model.

Rittman, III et al, as addressed previously, disclose an analogous RF system for treating tumors. In particular, the Rittman system includes the same basic RF probe, imaging and mapping system as set forth in the Johnson et al system. Rittman specifically teach that it is advantageous to provide predicted ablation mapping based on an applied dosage which can be compared to actual ablation images to predict and control the ablation of tissue (column 14).

To have provided the Johnson et al system with a means to display a predicted ablation model to estimate the amount of tissue damage resultant from a given dosage would have been an obvious consideration for one of ordinary skill in the art in view of the teaching of Rittman, III et al. To have further provided the Johnson et al system with multiple displays to compare the predicted model to the actual tissue ablation and use the mappings to control the amount of energy delivered to the probe during the procedure would have been an obvious consideration in view of the teaching of Rittman, III et al.

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Claims 1-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Desai (5,657,755) in view of the teaching of Rittman, III et al ('969).

Desai discloses a catheter device for the mapping and ablation of cardiac tissue. In particular, the device comprises a probe (i.e. catheter) having mapping sensors that may also be used to ablate tissue. The device is deployed to multiple locations within the heart tissue to provide a map of the tissue area and determine appropriate locations to ablate tissue (see Figure 5). Desai disclose providing a display showing the mapping locations, but fails to expressly teach providing an image including a predicted ablation image pertaining to a given dosage of ablation energy, as well as a comparative actual ablation image as set forth in the instant claims.

As asserted previously, Rittman, III et al teach that it is known to provide predictive models for an applied ablation dosage, as well as an actual mapping of the tissue as it is being ablated to provide the user with comparative imaging of the desired and actual results.

To have provided the Desai system with a more comprehensive imaging system to provide predicted ablation zones as well as actual ablation zones for controlling and comparing the ablation process would have been an obvious consideration for one of ordinary skill in the art in view of the teaching of Rittman, III et al.

Claim 41 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rittman, III et al ('969) in view of the teaching of Ben-Haim et al (6,690,963).

The Rittman system has been addressed previously. Rittman disclose the use of various imaging techniques for providing imaging of the probe assembly. However, Rittman fails to specifically disclose the use of sensor coils located in the probe so as to provide the feedback during ultrasound imaging.

Ben-Haim et al disclose a system for determining the location and orientation of a probe within the body, much like the Rittman et al system. In particular, Ben-Haim et al teach that the probe may be provided with sensor coils (Figure 2) to assist in determining the location and orientation of the device during imaging.

To have provided the Rittman, III et al system with sensor coils on the probe device to provide information regarding the location and orientation of the device within tissue during imaging would have been an obvious consideration for one of ordinary skill in the art in view of the teaching of Ben-Haim et al.

Claims 18 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al ('871) and Rittman, III et al ('969) and further in view of the teaching of Ben-Haim et al (6,690,963).

The combination of the Johnson et al system with the Rittman teaching has been addressed previously. Rittman and Johnson et al disclose the use of various imaging techniques for providing imaging of the probe assembly, but fail to specifically disclose the use of sensor coils located in the probe so as to provide the feedback during ultrasound imaging.

Ben-Haim et al disclose a system for determining the location and orientation of a probe within the body, much like the Rittman et al system. In particular, Ben-Haim et al teach that the probe may be provided with sensor coils (Figure 2) to assist in determining the location and orientation of the device during imaging.

To have provided the Johnson et al system, as modified by the teaching of Rittman, III et al, with sensor coils on the probe device to provide information regarding the location and orientation of the device within tissue during imaging would have been an obvious consideration for one of ordinary skill in the art in view of the teaching of Ben-Haim et al.

Conclusion

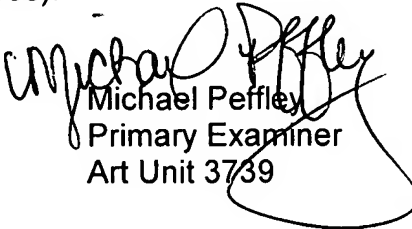
The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Rittman, III et al (6,506,189) discloses another tissue mapping/imaging/ablation device that provides the user with visual feedback of the ablation procedure. Panescu et al (5,546,940) discloses another cardiac ablation and mapping system that is used to create mapped images of heart tissue prior to ablation of tissue.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (571) 272-4770. The examiner can normally be reached on Mon-Fri from 6am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Michael Peffley
Primary Examiner
Art Unit 3739

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February 27, 2006